APR 16 2013

SIGN FRACTURE CARE INTERNATIONAL

451 Hills St, Suite B • Richland, WA 99354
P (509) 371-1107 • F (509) 371-1316

510(k) Summary

510(k) Submitter: SIGN Fracture Care International
451 Hills Street, Suite B
Richland, WA 99354

Establishment #: 3034525

Contact Person: Doug Donnelly,
Regulatory Affairs Manager
Phone: 509-371-1107
Fax: 509-371-1316
E-Mail: doug.donnelly@signfracturecare.org

Date Prepared: August 1, 2012
Regulatory Class: Class II
Panel: Orthopedic
Trade Name: SIGN Pediatric Fin Nail
Common Name: Pediatric Intramedullary Rod
Classification Name: Rod, Fixation, Intramedullary and Accessories 21 CFR 888.3020
Device Product Code: HSB

Substantial Equivalence Information
Biomet, Inc., Titanium Pediatric Femoral Nail (**K993956**)
SIGN Fin Nail (**K043200**)

Device Description
SIGN Pediatric Fin Nail is an Intramedullary Fixation Rod designed to be inserted into the medullary canal of the femur for fixation of fractures by aligning and stabilizing the bone fragments The SIGN Pediatric Fin Nails are available in a variety of lengths, shaft diameters, and fin diameters to accommodate a variety of patient anatomies. Each nail has a proximal bend and a slot at the proximal end to accept a solid 4.5mm diameter cortical bone screw for fixation and uses rigid distal fins for rotational stability. The Pediatric Fin Nail may be removed upon fracture healing. The Pediatric Fin Nail is a single use device, supplied non-sterile, and manufactured from stainless steel in accordance with ASTM F 138.

SIGN
FRACTURE CARE
INTERNATIONAL

451 Hills St, Suite B • Richland, WA 99354
P (509) 371-1107 • F (509) 371-1316

Indications for Use
The SIGN Pediatric Fin Nail is indicated for internal fixation of diaphyseal fractures of the femur, osteotomies, correction of malunions and nonunions on patients who are anatomically suited to receive the device.

Substantial Equivalence
The SIGN Pediatric Fin Nail is substantially equivalent to the Biomet, Titanium Pediatric Femoral Nail and the SIGN Fin Nail in design, performance, function and intended use. The safety and effectiveness of the SIGN Pediatric Fin Nail is also based on a long history of use of this type of device in the marketplace.

The differences of indication to the predicate devices are not critical to the surgical use of the device. Osteotomies can be described as deliberate diaphyseal fractures, which was already included as an indication of the predicate device. Also, malunions and nonunions are treated with a similar surgical approach as diaphyseal fractures. These differences do not affect the safety and effectiveness of the device because it is still being used in the same manner; to hold bone parts in alignment while they heal.

1. Comparison of Technological Characteristics

The predicate and proposed devices have a similar intended use and basic fundamental scientific technology and share the following similarities:

* Similar indications for use
* Similar design features
* Incorporate the same or similar materials
* Equivalent mechanical performance, based on intended use

Though the proposed device has features largely similar to those of the predicate devices, all of its features are not present on either predicate independently. This prompted non-clinical performance testing. For example, the SIGN Pediatric Fin Nail has similar length, material and fixation technique as the SIGN Fin Nail but the Nail diameter and semi-rigid design feature are similar to the Titanium Pediatric Femoral Nail

2. Performance Testing

The SIGN Pediatric Fin Nail was tested in a non-clinical setting (bench testing) to assess that no safety and effectiveness issues were raised with this device. The testing met all acceptance criteria and the results indicate that the SIGN Pediatric Fin Nail is functionally safe for its intended use. Specific testing performed included compression and torsion bench testing to evaluate the axial strength and rotational stability. In addition, fatigue tests simulating walking gait were performed to validate that the SIGN Pediatric Fin Nail design can withstand patient use until fracture consolidation occurs.

451 Hills St, Suite B • Richland, WA 99354
P (509) 371-1107 • F (509) 371-1316

The SIGN Pediatric Fin Nail is used with screws that are identical to screws cleared for other systems. Therefore, no new screw testing was needed to support substantial equivalence.

3. Conclusion

The data and information provided in this submission support the conclusion that the SIGN Pediatric Fin Nail is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 16, 2013

SIGN Fracture Care International
% Mr. Douglas Donnelly
Manager, Regulatory Affairs
451 Hills St. Suite B
Richland, Washington 99354

Re: K122823
Trade/Device Name: SIGN Pediatric Fin Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 29, 2013
Received: April 16, 2013

Dear Mr. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122823

Device Name: SIGN Pediatric Fin Nail

Indications for Use: The SIGN Pediatric Fin Nail is indicated for internal fixation of diaphyseal fractures of the femur, osteotomies, correction of malunions and nonunions on patients who are anatomically suited to receive the device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices